

significantly increased survival was observed associated with higher tumor transduction levels after 5-FC treatment compared to controls.

Conclusions: These results using Toca 511/5-FC prodrug activator gene therapy in preclinical models of disseminated ovarian cancer support future efforts toward clinical translation.

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Poster #42

Intraperitoneal chemotherapy is equally safe and effective in ovarian cancer patients with and without Germline BRCA1 or BRCA2 mutations

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Objectives: Intraperitoneal chemotherapy (IPC) achieves higher local drug concentrations and has demonstrated superiority in some settings to intravenous delivery for the treatment of epithelial ovarian cancer (OC). Because OC in patients with BRCA1 or BRCA2 (BRCA) mutations is hypersensitive to platinum agents, BRCA status may modify the efficacy of IPC. It is unknown whether BRCA haploinsufficiency in normal cells of mutation carriers could result in increased toxicity from platinum based IPC. The objective of this study was to compare the toxicity profiles and survival of OC patients with and without germline BRCA mutations who received IPC.

Methods: We conducted a retrospective review of the medical records of patients who received at least one cycle of IPC for the treatment of OC at a single center between 2005 and 2015. We restricted the review to patients who either carried BRCA mutations or had negative multigene testing. We abstracted demographic, clinical and tumor characteristics and compared characteristics between groups using t-tests for continuous data and chi-square tests or Fisher's exact tests as appropriate for categorical data. We constructed Kaplan-Meier curves for survival analysis. We had 80% power to detect a 25% difference in toxicity and a 62.5% survival difference.

Results: We identified 142 patients, 31 of whom had a BRCA mutation and 111 without mutations. The average age at diagnosis was 53 for BRCA patients and 62 for non-carriers ($p=0.003$). Histology and stage distributions were similar, as were the percentages of patients undergoing bowel surgery (38.7%). Most patients (74.2% in BRCA group and 91% in wildtype group) received IPC in the front-line setting, while the remainder did so for recurrences. BRCA carriers were more likely to have received chemotherapy for a prior malignancy (12.9% v 2.7%, $p=0.04$). Overall, 45% of patients in the BRCA group and 51.4% in the wildtype group experienced at least one chemotherapy-related toxicity ($p=0.54$). There was no difference between the two groups in rates of dose adjustments (13% v 18%, $p=0.51$) or IPC discontinuation (0% v 10%, $p=0.12$) due to toxicity. In the subgroup of patients who received front-line IPC ($n=124$), the median overall survival was 75.4 months for the BRCA group and 77.5 months for the wildtype group ($p=0.46$).

Conclusions: Germline BRCA mutation status does not appear to have a large impact on toxicity or survival in patients with OC treated with IPC. These findings should be replicated in larger studies.

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Poster #43

Pelvic disease control in patients undergoing vaginal brachytherapy for stage II endometrial cancer

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Objectives: To estimate the pelvic recurrence rate in patients with stage II endometrial cancer (EC) undergoing vaginal brachytherapy without pelvic external beam radiotherapy.

Methods: Data from women with pathology confirmed stage II EC were extracted from our institution's brachytherapy database from January 2006 to December 2012.

Results: From 2006-2012, 20 women with stage II EC underwent surgery with curative intent and adjuvant vaginal brachytherapy. Patients were followed for a median time of 87.5 months (range, 17.3-120.3 months). The median age at diagnosis was 62 (range, 49-76). The majority of specimens were of endometrioid histology (75%), with serous, clear cell, carcinosarcoma, and other representing 5%, 5%, 10%, and 5%, respectively. Lymphovascular invasion was noted in 10% of cases, with 45% Grade 1, 20% Grade 2, and 35% Grade 3. Twenty percent of patients received adjuvant chemotherapy and 90% underwent pelvic nodal dissection at the time of surgery. The 5 year-estimates for in-field vaginal, pelvic, and distant control were 85% (95% CI: 69%-100%), 90% (95% CI: 75%-100%), and 70% (95% CI: 50%-90%). The five-year overall survival (OS) estimate was 85% (95% CI: 69%-100%). We noted a trend towards reduced distant disease control in patients with non-endometrioid versus endometrioid histology with 5-year rates of 79% (95% CI: 58%-100%) versus 40% (95% CI: 0%-83%); ($p=0.11$). Five-year OS was significantly better in patients with distant disease control versus distant failure with 5-year rates of 100% (95% CI: 79%-100%) versus 63% (95% CI: 29%-97%); ($p=0.02$). No such OS association was seen for patients who experienced pelvic failure ($p=0.20$). Crude rates of Common Terminology Criteria for Adverse Events (CTCAE) grade 0 and 1 urinary toxicity were 85% and 15%. CTCAE grade 0 and 1 gastrointestinal (GI) toxicity were 65% and 35%. No patients developed grade 2 or greater urinary or GI toxicity by last follow-up. Vaginal stenosis/atrophy was seen in 15% of patients.

Conclusions: Vaginal brachytherapy is well-tolerated and associated with acceptable rates of pelvic disease progression in patients with stage II EC. Patients with stage II EC and non-endometrioid histology have a high-risk of distant recurrence and consideration of systemic therapy is warranted in this setting.

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Poster #44

Topical vaginal estrogen use and risk of endometrial hyperplasia or cancer

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Objectives: To estimate the yearly incidence rate of endometrial hyperplasia or cancer in women categorized by their unopposed topical vaginal estrogen (VE) prescriptions.

Methods: Women aged 46 years and older were identified from our institution's database from 2006-2012. ICD-9 diagnosis codes and our internal cancer registry were used to identify the first date of endometrial hyperplasia/cancer diagnosis. Pharmacy records were used to identify dispensed prescriptions for VE within 3 years prior to the reference date. The reference date used for dispensed estrogen or progesterone was defined as the index date for cases and December 31 for non-cases. Women exposed to systemic estrogen (SE) or progesterone within 2 years prior of the reference date were

excluded. The number of dispensed VE prescriptions was used to categorize women into 3 groups: “4 or more,” “1-3,” and “0”.

Results: Approximately 450,000-530,000 women in each year were included. The mean number per year of patients that dispensed “4 or more” was 11,327, “1-3” was 30,376, and “0” was 454,516. The overall average yearly disease incidence of endometrial hyperplasia/cancer in the “4 or more,” “1-3,” and “0” groups was 9.96, 10.25, and 9.96 (per 10,000 women), respectively.

Conclusions: The data suggests using unopposed topical vaginal estrogen is not associated with an increased risk of endometrial hyperplasia or cancer.

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Poster #45

Synchronous cervical and vulvar dysplasia – High likelihood in women who are immunocompromised

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Objectives: Dysplastic lesions of the cervix and vulva have similar risk factors. However, the incidence of cervical dysplasia is 10 times more than that of vulvar dysplasia suggesting high risk HPV induced transformation of the vulvar epithelium occurs less often than cervical epithelium. This implies there are novel factors required for the progression normal vulvar to dysplasia. The aim of this study was to evaluate the clinicopathologic characteristics that predispose patients to synchronous cervical and vulvar dysplasia/cancer.

Methods: We performed a case-control study on patients seen from January 2010 to October 2013 and diagnosed with cervical intraepithelial neoplasia (CIN) or cancer on excisional biopsy (cold knife cone or loop electrosurgical excision procedure) who also developed synchronous vulvar intraepithelial neoplasia or cancer. Clinical variables predisposing women to cervical and/or vulva dysplasia were evaluated. Number of lifetime sexual partners and age at coitarche were not readily available for statistical analysis. SPSS software was used to calculate the odds ratio (OR) for binary dependent variables.

Results: The average age was 37 year old in both subgroups of women with synchronous lesions as well as those with cervical dysplasia alone. Approximately 43% of the women who had cervical dysplasia alone had a BMI > 30kg/m² compared with 25% in those with synchronous lesions. There was no difference in the odds ratio of smoking, alcohol use, illicit drug use, OCP use, parity, hypertension, hyperlipidemia, diabetes and depression between women with cervical dysplasia alone versus those with cervical and vulvar dysplasia/cancer. The only statistically significant findings were found in those with immunosuppression or an HIV infection with an odds ratio of 18.9 (95% CI 7.9676 to 44.7392 with P value < 0.001).

Conclusions: Immunocompromised patients have a significantly higher likelihood of developing synchronous cervical and vulvar dysplasia. Our findings underscore the necessity of a complete examination of the lower genital tract especially in those who are immunocompromised.

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Poster #46

Invasive vulvar Extramammary Paget's Disease in the United States

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Objectives: Extramammary Paget's disease (EMPD) is an intra-epithelial neoplasm commonly found in the vulva. Large national databases are useful due to disease rarity, particularly for invasive forms of EMPD. We sought to assess the incidence, treatment modality, and outcomes in patients with invasive vulvar EMPD.

Methods: The National Cancer Institute's (NCI) Surveillance, Epidemiology and End Results (SEER) population-based cancer registries was searched for patients diagnosed with invasive Extramammary Paget's disease (ICD-O-3 histology code: 8542) of the vulva (ICD-O-3 topography code: C51.0-51.9) between 1992-2014. Incidence rate, demographics, survival, synchronous and secondary malignancies were analyzed.

Results: From 1992-2014, 1110 patients were diagnosed with invasive vulvar EMPD: of those, 74.0% had localized disease, 13.2% regional disease, 1.5% distant disease and 11.3% were unstaged. The overall annual incidence of invasive vulvar EMPD was 0.35 per 100,000 person years: rates have increased more than 2-fold since 1992 (1992: 0.19 per 100,000 person years to 0.50 per 100,000 person years in 2014). Surgery was the primary treatment for most (n=898, 80.9%) patients, with 24 (2.2%) having surgery and radiation. In 4 cases (0.4%) radiation alone was used: 184 (16.6%) did not undergo radiation or surgery. Five-year cancer specific survival (CSS) overall was 94.2% and was closely related to stage. Patients with localized disease or those who were unstaged had the best survival (P<0.0001). Patients who presented with distant disease had significantly worse outcomes vs. local disease (HR: 85.911 (29.8-248) p<0.0001). CSS was 95.7% in patients undergoing surgery alone, 90.0% observation, and 57.9% surgery and radiation (p<0.0001). Synchronous cancers (diagnosed within 12 months of EMPD) were observed in 30 cases (2.7%), and 161 patients (14.5%) developed a secondary malignancy (diagnosed >12 months from EMPD) malignancy. The most common synchronous and secondary cancers were gastrointestinal, breast, or genitourinary.

Conclusions: The incidence of invasive vulvar EMPD has increased over time. Cancer specific survival is excellent for localized disease, but those with metastatic disease are in need of novel therapies: radiation appears to have limited benefit. A large number of EMPD patients (14.5%) will develop a secondary malignancy and should undergo site specific preventative health screens during recurrence surveillance.

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Poster #47

Primary chemoradiation therapy for locally advanced cervical cancer: Outcomes and disparities

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Objectives: To identify disparities in timely receipt of primary chemoradiation in patients with locally invasive cervical cancer.

Methods: The National Cancer Database (NCDB) was queried to identify stage II-IVA cervical cancer patients diagnosed in the United States between 2004 to 2015 and receiving chemoradiation (CRT) as primary treatment. Patients were divided into those whose duration of CRT treatment was ≤8 weeks and >8 weeks. The primary outcome was overall survival. Patients were stratified by demographic factors including age, race/ethnicity, insurance status, distance from hospital, and hospital setting, as well as clinical factors including stage and grade.

Results: We identified 21,579 women. 11,265 women (52.2%) completed chemoradiation therapy in ≤8 weeks. The median OS was longer for patients who completed CRT in ≤8 weeks (95.1 vs 73.7 months, p \$63,000. Patients with Medicaid/Medicare insurance (OR 0.85, 95% CI 0.80-0.90) were also less likely to complete CRT in ≤8 weeks compared to those with private insurance. Patients with stage III disease (OR 0.81, 95% CI 0.77-0.85) were less likely to complete CRT in ≤8 weeks than those with stage II disease. Age, distance from